IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ALNYLAM PHARMACEUTICALS, INC., Plaintiff, v. MODERNA, INC., MODERNA TX, INC., and MODERNA US, INC., Defendants.	C.A. No. 22-cv-925-CFC (CONSOLIDATED WITH LEAD CASE 22-cv-335-CFC)

MODERNA'S COUNTERCLAIMS AND ANSWER TO THE COMPLAINT

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Defendants/Counterclaim-Plaintiffs Moderna, Inc., Moderna TX, Inc., and Moderna US, Inc. (collectively, "Moderna") by and through their attorneys, bring the following Counterclaims against Plaintiff/Counterclaim-Defendant Alnylam Pharmaceuticals, Inc. ("Alnylam"):

FACTUAL BACKGROUND

1. Moderna brings these Counterclaims in response to Alnylam's Complaint, which baselessly seeks to profit from Moderna's innovations that led to its groundbreaking mRNA-1273 COVID-19 Vaccine ("SPIKEVAX®"). Specifically, Moderna asks this Court to declare the following: (a) SPIKEVAX® does not infringe the '979 Patent; (b) the '979 Patent is invalid; and (c) Alnylam has

no claim against Moderna to the extent Moderna used or manufactured SPIKEVAX® "for the Government" and "with the authorization or consent of the Government" under 28 U.S.C. § 1498. In short, this lawsuit will confirm that Moderna and its scientists, employees, and collaborators are the true innovators in the mRNA delivery technology that led to the lifesaving SPIKEVAX® vaccine. Alnylam played no role in Moderna's significant accomplishments.

A. Moderna's Development of mRNA Medicines Using Lipid Nanoparticle Technology

2. For a decade before COVID-19 emerged, Moderna had been pioneering a new class of medicines made of messenger RNA, or mRNA, and developed its own platform technologies that could deliver mRNA in a variety of therapeutic and prophylactic applications, including vaccines. These mRNA medicines have the potential to treat and prevent a wide range of diseases—from infectious diseases like influenza and HIV, to autoimmune and cardiovascular diseases and rare forms of cancer. Over the past twelve years, Moderna has worked diligently in its laboratories to pioneer a number of fundamental breakthroughs in the field of mRNA technology. These discoveries span all aspects of mRNA medicines—from the characteristics and design of the mRNA itself and the protein it encodes, to the technologies to deliver mRNA to patients safely and effectively.

3. Included among the mRNA advancements that Moderna developed over years of extensive work is its proprietary lipid nanoparticle ("LNP") delivery

technologies to provide the mRNA for delivery. The LNPs function to protect the mRNA and deliver it into cells. Critical to the LNP delivery technology used in SPIKEVAX® is Moderna's proprietary lipid, SM-102. Moderna scientist Dr. Kerry Benenato discovered SM-102. Dr. Benenato and her team conducted extensive work to discover a lipid for use in an LNP that would address the issues of being able to protect the delivery of fragile mRNA to the right location in the body, effectively deliver the mRNA to the cells of interest, and then biodegrade so as not to cause tolerability issues. This was no small feat.

4. Moderna invested years of work and resources to develop LNPs that are tailored to work with mRNA. Those efforts included developing novel proprietary lipids, including SM-102, and improving LNP manufacturing processes.

B. Moderna's development and Sale of SPIKEVAX®

5. The SARS-CoV2 virus, which causes COVID-19, was first detected in December 2019. On January 10, 2020, the genetic sequence of the SARS-CoV-2 virus became public. Leveraging its decade of research and proprietary technologies, Moderna quickly responded when the pandemic struck, swiftly developing, manufacturing, and providing doses of SPIKEVAX® to people around the world. SPIKEVAX®, also referred to as the mRNA-1273 vaccine, uses Moderna's proprietary LNP delivery technology that Moderna developed and described years earlier. For that groundbreaking work, Moderna's scientists were recently honored

by the American Chemistry Society's 2022 Heroes of Chemistry Award, the highest honor for industrial chemical scientists, recognizing their "work developing formulations that protect against . . . COVID-19."[1]

6. Following the declaration of a public health emergency, Moderna entered into numerous agreements with the U.S. Government regarding SPIKEVAX®. In April 2020, Moderna entered into a grant agreement with the Biomedical Advanced Research and Development Authority ("BARDA")—an office of HHS—to support clinical development of the mRNA-1273 vaccine. BARDA chose to partner with Moderna to develop SPIKEVAX® because "Moderna's mRNA-based vaccine platform has been used to rapidly prepare vaccine candidates against Cytomegalovirus, Zika, Respiratory Syncytial Virus, Influenza, Human Metapneumovirus and Parainfluenza virus."[2]

7. Once Moderna had obtained promising clinical results, on August 9, 2020, ModernaTX, Inc. entered into a supply contract with the Army Contracting Command of the U.S. Department of Defense, Contract No. W911QY20C0100

[1] Nina Notman, Chemists are Recognized for Their Contributions to Sustainable Packaging, Dental Cements, Breast Cancer Treatments, and Formulations that Protect Against or Treat COVID-19, C&EN, https://pubs.acs.org/doi/10.1021/cen-10028-acsnews2.

[2] Contract No. 75A50120000034 Development of an mRNA Vaccine for SARS-CoV-2, § C.1 at 9, https://www.hhs.gov/sites/default/files/moderna-75a50120c00034.pdf.

("C0100 Contract").[3] Under the C0100 Contract, Moderna was obligated to produce and deliver doses of SPIKEVAX® to the U.S. Government, with the option to supply additional doses.[4] The C0100 Contract specifically states that Moderna manufactured SPIKEVAX® doses "for the United States Government."[5] The C0100 contract also incorporates by reference FAR 52.227-1, entitled "Authorization and Consent."[6]

8. Moderna received emergency use authorization for SPIKEVAX® in the U.S. from the Food & Drug Administration ("FDA") on December 16, 2020, less than a year after beginning development. Promptly thereafter, Moderna shipped SPIKEVAX® doses to the U.S. Government pursuant to the C0100 Contract. On January 31, 2022, Moderna received full approval from the FDA for its Biologics License Application for SPIKEVAX®.[7]

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[3] Army Contracting Command of the U.S. Department of Defense, Contract No. W911QY20C0100, https://www.hhs.gov/sites/default/files/moderna-large-scale-production-sars-cov-2-vaccine.pdf.
[4] *Id.*
[5] *Id.* at 19.
[6] *Id.* at 46 (also incorporating FAR clause 52.227-1 Alternate I).
[7] Colleen Hussey, Moderna Receives Full U.S. FDA Approval for COVID-19 Vaccine SPIKEVAX, https://investors.modernatx.com/news/news-details/2022/Moderna-Receives-Full-U.S.-FDA-Approval-for-COVID-19-Vaccine-Spikevax/default.aspx.

C. Alnylam does not Develop mRNA Medicines

9. In contrast to Moderna's mission to deliver the greatest possible impact to people through mRNA medicines, Alnylam has based its entire business model on another type of RNA called small interfering RNA ("siRNA"). This distinction is notable because mRNA and siRNA are markedly different. Structurally, mRNA is significantly larger than siRNA; this size difference makes it much harder to package mRNA into drug delivery vehicles (like LNPs). Functionally, mRNA promotes the expression of proteins in cells; siRNA, by contrast, shuts down cellular protein expression in a process called RNA interference ("RNAi").

10. Unlike Moderna, Alnylam has not focused any of its drug development efforts towards mRNA therapeutics. To be sure, *every* FDA-approved product Alnylam has brought to market involves methods of delivering siRNA—not mRNA.

11. Alnylam's website is also telling. Its front webpage describes Alnylam as "THE LEADING RNAi THERAPEUTICS COMPANY."[8] Alnylam's website goes on to explain that its two therapeutic delivery platforms—lipid nanoparticles ("LNPs," *i.e.*, the subject of this lawsuit) and GalNAc conjugates—"enable delivery of small interfering RNA (siRNA) to target tissues."[9] Nowhere on its website does Alnylam describe using either platform to deliver mRNA.

[8] https://www.alnylam.com/.
[9] https://www.alnylam.com/our-science/sirna-delivery-platforms.

12. The asserted patent in this suit further illustrates that Alnylam has not historically focused on mRNA. The '979 Patent is titled "Biodegradable Lipids for the Delivery of Active Agents." '979 Patent at 1. The only "Active Agents" the '979 Patent's written description includes, however, are siRNA and miRNA. In fact, nowhere in the hundreds of pages constituting the '979 Patent's written description or claims does the term "mRNA" appear.

13. At first blush, it may appear as though the same LNPs that effectively deliver siRNA into target cells would work well in therapeutic mRNA applications. This could not be further from the truth. As Romesh Subramanian (a former Moderna-affiliated scientist) stated, "off-the-shelf LNP formulations designed for siRNA" did not work well for mRNA delivery due to the significant size differences between the two molecules: "siRNA molecules are . . . about 20 nucleotides each," whereas "mRNA . . . can easily span thousands of nucleotides, wind into complex shapes, and change the properties of the LNP in ways that are hard to predict." D.I. 1, Ex. 15 at 675.

14. Tellingly, Alnylam never developed a cationic lipid for use in an LNP that was capable of delivering mRNA, let alone manufactured or sold any mRNA-based FDA-approved product.

D. Alnylam Tries to Claim SM-102, Which It Did Not Invent

15. Failing to develop any cationic lipid or LNP technology for delivering mRNA, Alnylam instead improperly expanded the scope of its patent estate in an attempt to cover the inventions of others, including pioneers like Moderna.

16. The '979 Patent is directed to specific cationic lipids, which are quite different than the proprietary lipid Moderna's scientists discovered, SM-102. Alnylam filed the original application (PCT/US2012/068491) underlying the '979 Patent in 2012. From that application, Alnylam sought and was issued claims to certain cationic lipids, none of which covered SM-102.

17. Although it originally filed its PCT application in 2012, Alnylam did not seek patent claims that purportedly cover SPIKEVAX® until *after* Moderna publicly released SM-102's structure in 2020. Only then did Alnylam attempt to cobble together claims it hoped would cover Moderna's proprietary SM-102 lipid and its use in Moderna's groundbreaking LNP-based mRNA delivery technology. But those claims are fatally flawed, having been stretched far beyond the patents' disclosure and previously described prior art.

PARTIES

18. Moderna, Inc. is a company organized and existing under the laws of the State of Delaware with a principal place of business at 200 Technology Square, Cambridge, Massachusetts 02139.

19. ModernaTX, Inc. is a company organized and existing under the laws of the State of Delaware with a principal place of business at 200 Technology Square, Cambridge, Massachusetts 02139.

20. Moderna US, Inc. is a company organized and existing under the laws of the State of Delaware with a principal place of business at 200 Technology Square, Cambridge, Massachusetts 02139.

21. On information and belief, Alnylam is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 675 West Kendall Street, Henri A. Termeer Square, Cambridge, Massachusetts 02142.

NATURE OF THE ACTION

22. Moderna seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100 et *seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, that U.S. Patent No. 11,382,979 (the "'979 Patent") is invalid and/or not infringed.

JURISDICTION AND VENUE

23. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 based on an actual controversy among the parties arising under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*

24. Personal jurisdiction over Alnylam is proper because Alnylam is a corporation organized and existing under the laws of the State of Delaware, and because Alnylam has consented to the personal jurisdiction of the Court by commencing its action for patent infringement in this Judicial District, as set forth in its Complaint.

25. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400 as Alnylam is a corporation organized and existing under the laws of the State of Delaware, and by virtue of Alnylam's filing of this lawsuit in this venue.

26. There is an actual justiciable controversy among the parties concerning non-infringement and invalidity of the '979 Patent.

COUNT I
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '979 PATENT

27. Moderna repeats and incorporates Paragraphs 1-26 as if fully set forth herein.

28. Alnylam has brought claims against Moderna alleging SPIKEVAX® infringes the '979 Patent.

29. A real, immediate, and justiciable controversy exists between Alnylam and Moderna regarding Moderna's alleged infringement of the '979 Patent.

30. Moderna has not infringed and is not infringing any valid claim of the '979 Patent, willfully or otherwise, directly or indirectly, either literally or by

application of the doctrine of equivalents. For example, SPIKEVAX® does not meet each and every element of independent claim 1 of the '979 Patent at least because it does not contain a lipid particle comprising the claimed cationic lipid, and dependent asserted claims 2-3, and 5-14 of the '979 Patent depend from claim 1. Also, SPIKEVAX® does not meet each and every element of independent claim 18 of the '979 Patent at least because it does not involve a method for preparing the claimed lipid particle mixture and dependent asserted claims 19-20 and 22-30 of the '979 Patent depend from claim 18.

31. Moderna is entitled to a declaratory judgment that Moderna does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid claim of the '979 Patent, either literally or under the doctrine of equivalents.

COUNT II
DECLARATORY JUDGMENT OF INVALIDITY OF THE '979 PATENT

32. Moderna repeats and incorporates Paragraphs 1-31 as if fully set forth herein.

33. Alnylam has brought claims against Moderna alleging infringement of at least claim 18 of the '979 Patent.

34. Moderna alleges that the claims of the '979 Patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or any

judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

35. Moderna is entitled to a declaratory judgment from this Court that the '979 Patent is invalid.

COUNT III
DECLARATORY JUDGMENT UNDER 28 U.S.C. § 1498

36. Moderna repeats and incorporates Paragraphs 1-35 as if fully set forth herein.[10]

37. Under 28 U.S.C. § 1498(a), Alnylam has no claim against Moderna to the extent that, pursuant to the C0100 Contract, any use or manufacture of doses of SPIKEVAX® were made "for the Government" and "with the authorization or consent of the Government".

38. Moderna is informed and believes, and based thereon alleges, that Alnylam disputes that Alnylam has no claim against Moderna to the extent that, pursuant to the C0100 Contract, any use or manufacture of SPIKEVAX® was done for the U.S. Government and with the authorization or consent of the U.S. Government.

[10] Moderna incorporates by reference its briefing concerning Moderna's Partial Motion to Dismiss Pursuant to Federal Rule of Civil Procedure 12(b)(6) and the U.S. Government's Statement of Interest concerning 28 U.S.C. § 1498 and SPIKEVAX® doses made pursuant to the C0100 Contract.

39. By virtue of the above facts, an actual controversy has arisen and now exists between Moderna and Alnylam as to whether Alnylam has no claim against Moderna to the extent that, pursuant to the C0100 Contract, any use or manufacture of SPIKEVAX® was done for the U.S. Government and with the authorization or consent of the U.S. Government.

40. Moderna requests a judicial determination that Alnylam has no claim against Moderna to the extent that, pursuant to the C0100 Contract, any use or manufacture of SPIKEVAX® was done with the authorization and consent of the U.S. Government. Such a declaratory judgment is necessary and appropriate at this time in order to determine the rights and legal relations of the parties, pursuant to 28 U.S.C. § 2201.

RELIEF REQUESTED

WHEREFORE, Moderna respectfully requests that the Court enter a Judgment and Order in their favor and against Alnylam as follows:

(a) Dismissing Alnylam's Complaint with prejudice and denying each and every prayer for relief contained therein;

(b) Declaring that Moderna does not infringe any claim of the '979 Patent;

(c) Declaring that the manufacture, use, offer to sell, and sale of the SPIKEVAX® vaccine within the United States, and its importation into the United States, does not infringe any claim of the '979 Patent;

(d) Declaring that the claims of the '979 Patent are invalid;

(e) Declaring that Alnylam and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Moderna or any of their customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Moderna, or charging any of them either orally or in writing with infringement of the '979 Patent;

(j) Declaring that Alnylam has no claim against Moderna to the extent that, pursuant to the C0100 Contract, any use or manufacture of SPIKEVAX® was done for the U.S. Government and with the authorization or consent of the U.S. Government;

(k) Awarding Moderna its attorneys' fees, together with costs and disbursements, including because this case is exceptional under 35 U.S.C. § 285; and

(l) Awarding such other and further relief as the Court deems justified.

* * *

ANSWER

Moderna, Inc., Moderna TX, Inc., and Moderna US, Inc. (collectively "Moderna") by and through their undersigned attorneys, hereby respond to the

allegations contained in the Complaint filed by Alnylam Pharmaceuticals, Inc. ("Alnylam" or "Plaintiff") and state their defenses to the claims asserted against it. To the extent unnumbered headings contained in the Complaint purport to contain allegations supporting Plaintiff's claims, they are denied.

NATURE OF THE ACTION

1. Alnylam is a pioneering RNA therapeutics company based in Cambridge, Massachusetts. Over a decade ago, Alnylam invented a breakthrough class of cationic biodegradable lipids used to form lipid nanoparticles ("LNP") that carry and safely deliver in the body RNA-based therapeutics or vaccines (the "Alnylam LNP Technology"). The Alnylam LNP Technology is foundational to the success of the recently-developed messenger RNA ("mRNA") based COVID vaccines. The United States Patent Office recognized Alnylam's inventive work, issuing United States Patent No. 11,246,979 (the "'979 Patent") that protects the Alnylam LNP Technology. (Exhibit 1.)

ANSWER: Moderna admits that the United States Patent Office issued the '979 Patent, but denies that this patent is valid under Title 35 of the United States Code. Moderna denies that any technology claimed by the '979 Patent contributed in any way to the success of SPIKEVAX® developed by Moderna. Moderna otherwise lacks the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1 and therefore denies the allegations.

2. Moderna's mRNA COVID-19 Vaccine uses a cationic biodegradable lipid covered by '979 Patent. Specifically, Moderna infringes Alnylam's '979 Patent through its SM-102 cationic biodegradable lipid formulated into LNPs that protect and safely deliver the vaccine's mRNA. Moderna executives have described the infringing SM-102 biodegradable lipid as the "unsung hero" of its COVID-19 Vaccine.

ANSWER: Paragraph 2 states legal conclusions to which no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 2.

3. Moderna has been aware of the Alnylam LNP Technology since at least early 2014, when Alnylam and Moderna entered into a business discussion regarding a license to Alnylam technology including the Alnylam LNP Technology. Alnylam brings this action to recover monetary compensation for Moderna's unlicensed use of Alnylam's '979 Patent. Alnylam does not seek injunctive relief under 35 U.S.C. § 283 against such use.

ANSWER: Moderna admits that the Complaint (D.I. 1) purports to state that Alnylam does not seek injunctive relief under 35 U.S.C. § 283. Moderna denies all of the remaining allegations of Paragraph 3.

THE PARTIES

4. Plaintiff Alnylam is a corporation organized under the laws of the State of Delaware with a principal place of business at 675 West Kendall Street, Henri A. Termeer Square, Cambridge, Massachusetts 02142. Founded in 2002, Alnylam is a groundbreaking life science company that has worked to harness the potential of RNA interference ("RNAi") therapeutics to transform the lives of people living with diseases that have limited or inadequate treatment options. Utilizing an earlier version of in licensed LNP Technology, in 2018 Alnylam delivered the world's first approved RNAi therapeutic, ONPATTRO® (patisiran). ONPATTRO® is currently approved for the treatment of polyneuropathy caused by an illness called hereditary ATTR (hATTR) amyloidosis. Alnylam has developed an additional delivery modality distinct from the LNP Technology, termed GalNAc Delivery, which is utilized in three marketed products, GIVLAARI® (givosiran), approved in 2019, and OXLUMO® (lumasiran), approved in 2020, both marketed by Alnylam and LEQVIO®(inclisiran), approved in 2021, developed initially by Alnylam and licensed to Novartis.

ANSWER: On information and belief, Moderna admits that Alnylam is a Delaware corporation with a principal place of business at 675 West Kendall Street,

Henri A. Termeer Square, Cambridge Massachusetts 02142. Moderna otherwise lacks the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 4 and therefore denies the allegations.

5. Alnylam has a long history of licensing or offering to license to third parties its intellectual property, including the Alnylam LNP Technology and the GalNAc Technology.

ANSWER: Moderna lacks the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 5 and therefore denies the allegations.

6. Upon information and belief, Defendant Moderna, Inc. is a company organized under the laws of the State of Delaware with a principal place of business at 200 Technology Square, Cambridge, Massachusetts 02139. Upon information and belief, Defendant Moderna, Inc. was previously known as Moderna Therapeutics, Inc. Upon information and belief, Defendant Moderna, Inc., is the parent company of the other Defendants and recognizes the revenue from sales of Moderna's COVID-19 vaccine. (Exhibit 3 at 98-100.)

ANSWER: Moderna admits that Moderna, Inc. is a Delaware corporation with a principal place of business at 200 Technology Square, Cambridge, Massachusetts 02139. Moderna admits that Moderna, Inc. was previously known as Moderna Therapeutics, Inc. and is the parent company of ModernaTX, Inc. and Moderna US, Inc. Moderna, Inc. admits that Exhibit 3 at 98-100 purports to be Moderna, Inc.'s 2021 10-K filing with the U.S. Securities and Exchange Commission that appears to show revenue from sales of SPIKEVAX®. Moderna denies the remaining allegations of Paragraph 6.

7. Upon information and belief, Defendant ModernaTX, Inc. is a company organized under the laws of the State of Delaware with a principal place of business at 200 Technology Square, Cambridge, Massachusetts 02139. Upon information and belief, Defendant ModernaTX, Inc. is a wholly owned subsidiary of Defendant Moderna, Inc. The FDA granted the Biologic License Approval ("BLA") for SPIKEVAX® to Defendant ModernaTX, Inc. (Exhibit 4 at 3). Defendant ModernaTX, Inc. is listed as the entity to contact in the prescribing information for SPIKEVAX®. (Exhibit 5 at 1.) According to the prescribing information, SPIKEVAX® is a trademark of Defendant ModernaTX, Inc. (*Id.* at 17).

ANSWER: Moderna admits that ModernaTX, Inc. is a Delaware corporation with a principal place of business at 200 Technology Square, Cambridge, Massachusetts 02139. Moderna admits that ModernaTX, Inc. is a wholly owned subsidiary of Moderna, Inc. Moderna states that Exhibit 4 is an FDA News Release titled "Coronavirus (COVID-19) Update: FDA Takes Key Action By Approving Second COVID-19 Vaccine," published in 2022 and available at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine. Exhibit 4 states that FDA granted the BLA for SPIKEVAX® to ModernaTX, Inc. Exhibit 4 at 3. Moderna admits that Exhibit 5 purports to be a January 2022 version of the prescribing information for SPIKEVAX®, as well as purports to list ModernaTX as the entity to contact for suspected adverse reactions. Exhibit 5 at 1. Moderna further admits that Exhibit 5 purports to describe SPIKEVAX® as a trademark of ModernaTX, Inc. *Id.* at 17. Moderna denies the remaining allegations in Paragraph 7.

8. Upon information and belief, Defendant Moderna US, Inc. is a company organized under the laws of the State of Delaware with a principal place of business at 200 Technology Square, Cambridge, Massachusetts 02139. Upon information and belief, Defendant Moderna US, Inc. is a wholly-owned subsidiary of Defendant Moderna, Inc. Defendant Moderna US, Inc. is listed in the prescribing information as the entity manufacturing SPIKEVAX®. (Exhibit 5 at 17.)

ANSWER: Moderna admits that Moderna US, Inc. is a Delaware corporation with a principal place of business at 200 Technology Square, Cambridge, Massachusetts 02139. Moderna admits that Moderna US, Inc. is a wholly-owned subsidiary of Moderna, Inc. Moderna states that Exhibit 5 purports to be a January 2022 version of the prescribing information for SPIKEVAX® that indicates SPIKEVAX® is "[m]anufactured *for*" (not *by*) Moderna US, Inc. Exhibit 5 at 17 (emphasis added). Moderna denies the remaining allegations in Paragraph 8.

9. On information and belief, Defendants Moderna Inc., ModernaTX, and Moderna US, Inc. are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, manufacturing, sales, offers for sale, and distribution of Moderna's COVID-19 Vaccine.

ANSWER: Paragraph 9 states legal conclusions to which no response is required. To the extent a response is required, Moderna denies the allegations of Paragraph 9.

JURISDICTION AND VENUE

10. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*

ANSWER: Paragraph 10 states legal conclusions to which no response is required. To the extent a response is required, Moderna admits that the Complaint

purports to state a claim for infringement arising under the patent laws of the United States 35 U.S.C. § 1, *et seq*. Moderna denies the remaining allegations of Paragraph 10.

11. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) because this is a civil action arising under the Patent Act.

ANSWER: Paragraph 11 states legal conclusions to which no response is required. To the extent a response is required and for purposes of this action only, Moderna does not contest that this Court has subject matter jurisdiction over this action.

12. This Court has personal jurisdiction over Defendant Moderna, Inc., Defendant ModernaTX, Inc., and Defendant Moderna US, Inc. because all three are Delaware corporations.

ANSWER: Paragraph 12 states legal conclusions to which no response is required. To the extent a response is required, Moderna does not contest that the Court has personal jurisdiction over Moderna, Inc., ModernaTX, Inc. and Moderna US, Inc., solely for purposes of this action.

13. This Court also has jurisdiction over Defendant Moderna, Inc. because, upon information and belief, it directly or indirectly makes, uses, offers for sale, and/or sells its COVID-19 Vaccine, made using SM-102, throughout the United States, including in this judicial district.

ANSWER: Paragraph 13 states legal conclusions to which no response is required. To the extent a response is required, Moderna does not contest that the Court has personal jurisdiction over Moderna, Inc., ModernaTX, Inc., and Moderna

US, Inc., solely for purposes of this action. Moderna denies that SPIKEVAX®, made using SM-102, infringes the '979 Patent directly or indirectly. Moderna denies the remaining allegations of Paragraph 13.

14. This Court also has jurisdiction over Defendant ModernaTX, Inc. because, upon information and belief, it directly or indirectly makes, uses, offers for sale, and/or sells its COVID-19 Vaccine, made using SM-102, throughout the United States, including in this judicial district.

ANSWER: Paragraph 14 states legal conclusions to which no response is required. To the extent a response is required, Moderna does not contest that the Court has personal jurisdiction over Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc., solely for purposes of this action. Moderna denies that SPIKEVAX®, made using SM-102, infringes the '979 Patent directly or indirectly. Moderna denies the remaining allegations of Paragraph 14.

15. This Court also has jurisdiction over Defendant Moderna US, Inc. because, upon information and belief, it directly or indirectly makes, uses, offers for sale, and/or sells its COVID-19 Vaccine, made using SM-102, throughout the United States, including in this judicial district.

ANSWER: Paragraph 15 states legal conclusions to which no response is required. To the extent a response is required, Moderna does not contest that the Court has personal jurisdiction over Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc., solely for purposes of this action. Moderna denies that SPIKEVAX®, made using SM-102, infringes the '979 Patent directly or indirectly. Moderna denies the remaining allegations of Paragraph 15.

16. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Defendant Moderna, Inc., Defendant ModernaTX, Inc., and Defendant Moderna US, Inc. are Delaware corporations.

ANSWER: Paragraph 16 states legal conclusions to which no response is required. To the extent a response is required, Moderna does not content that Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. are Delaware corporations and that venue is proper for purposes of this action only.

BACKGROUND

A. RNA THERAPEUTICS

17. The promise of RNA-based therapeutics (including RNAi and mRNA) has long been known, but scientists have struggled for decades to translate the promise into successful human therapeutics. The main challenge scientists around the world struggled with was how to deliver the fragile, negatively charged RNA into the body's cells in a safe, effective, and non-toxic way. (Exhibit 15 at 1-2.)

ANSWER: The allegations of Paragraph 17 purport to rely on Exhibit 15, pages 1-2, which speaks for itself. At least because of the scope, breadth, and vagueness of this allegation, Moderna lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 17 and therefore denies the allegations.

18. One approach was to develop a lipid system for use with RNA-based therapeutics. These lipids would form a nanoparticle, called a Lipid Nanoparticle or LNP. The LNPs would encapsulate and protect the fragile RNA upon administration to the body so the RNA could be delivered to the cells where the RNA would provide its therapeutic effect. Because the RNA is negatively charged, the lipids had to be positively charged (cationic) to create the protective bubble around the RNA. Cationic lipids do not exist in nature, and therefore had to be synthesized. There

were toxicity issues with early attempts to use them in therapeutics due to the high dose of LNP needed to be effective.

ANSWER: At least because of the scope, breadth, and vagueness of this allegation, Moderna lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 18 and therefore denies the allegations.

19. To harness the full promise and power of LNPs to deliver revolutionary RNA therapies, scientists needed to develop a more potent LNP system that could safely and effectively deliver the RNA to the target cells, and then be metabolized and eliminated from the body.

ANSWER: At least because of the scope, breadth, and vagueness of this allegation, Moderna lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 19 and therefore denies the allegations.

20. Alnylam overcame some of the issues associated with earlier versions of LNP using an in-licensed LNP system containing the cationic lipid compound known as MC3, a highly potent molecule. With MC3, Alnylam developed ONPATTRO®. MC3, while safe and effective, is more stable in the body and thus has a relatively long half-life. Alnylam recognized the need for further improvements in LNP technology and internally embarked on a research program to develop a new class of lipids with improved properties.

ANSWER: Moderna admits that Alnylam markets ONPATTRO®, an siRNA drug. At least because of the scope, breadth, and vagueness of this allegation, Moderna lacks the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 20 and therefore denies the allegations.

B. ALNYLAM'S BREAKTHROUGH BIODEGRADABLE LNP TECHNOLOGY FOR DELIVERY OF RNA TO CELLS

21. Over a decade ago, Alnylam scientists solved these pressing issues by inventing a new class of non-natural LNPs comprising a cationic lipid with biodegradable groups (*i.e.,* the Alnylam LNP Technology). LNPs with these biodegradable groups protect the RNA until delivery to inside the cell, and then are metabolized and eliminated from the body ensuring no dose-limiting toxicity. Alnylam's seminal work to create these novel biodegradable LNPs has been employed in potential RNA therapeutics in development and now mRNA-based vaccines.

ANSWER: At least because of the scope, breadth, and vagueness of this allegation, Moderna lacks the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 21 and therefore denies the allegations.

C. THE PATENT-IN-SUIT

22. Alnylam filed a series of provisional and utility patent applications on its novel cationic biodegradable lipids. Utility applications disclosing these novel cationic biodegradable lipids published on February 2, 2012 and August 1, 2013. Twenty-two patents world-wide have issued to Alnylam based on these groundbreaking inventions described in its provisional and utility patent applications.

ANSWER: Paragraph 22 states legal conclusions to which no response is required. To the extent a response is required, Moderna lacks the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 22 and therefore deny the allegations.

23. On February 15, 2022, The United States Patent & Trademark Office issued the '979 Patent, entitled "Biodegradable Lipids for the Delivery of Active Agents." The '979 Patent issued to Alnylam as assignee of the named inventors Martin Maier, Muthusamy Jayaraman, Akin Akinc, Shigeo Matsuda, Pachamuthu Kandasamy, Kallanthottathil G. Rajeev, and Muthiah Manoharan.

ANSWER: Moderna admits that the '979 Patent is titled "Biodegradable Lipids for the Delivery of Active Agents" and that an issuance date of February 15, 2022 appears on the face of the '979 Patent. Moderna admits that on the face of the '979 Patent, Alnylam is listed as an assignee, but Moderna lacks and information or knowledge whether this is true. Moderna further admits that on the face of the '979 Patent the names Martin Maier, Muthusamy Jayaraman, Akin Akinc, Shigeo Matsuda, Pachamuthu Kandasamy, Kallanthottathil G. Rajeev, and Muthiah Manoharan are listed as inventors, but Moderna lacks and information or knowledge whether this is true.

24. The '979 Patent claims a class of cationic biodegradable lipids that can be used in the formation of LNPs for the delivery of an active agent, including mRNA. Each cationic lipid contains one or more biodegradable group.

ANSWER: Paragraph 24 states legal conclusions to which no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 24.

25. Independent claim 18 of the '979 Patent is representative and recites:

> A cationic lipid comprising a primary group and two biodegradable hydrophobic tails, wherein
>
> the primary group comprises (i) a head group that optionally comprises a primary, secondary, or tertiary amine, and (ii) a central moiety to which the head group and the two biodegradable hydrophobic tails are directly bonded;
>
> the central moiety is a central carbon or nitrogen atom;

each biodegradable hydrophobic tail independently has the formula -(hydrophobic chain)(biodegradable group)-(hydrophobic chain), wherein the biodegradable group is -OC(O)- or -C(O)O-;

for at least one biodegradable hydrophobic tail, the terminal hydrophobic chain in the biodegradable hydrophobic tail is a branched alkyl, where the branching occurs at the α-position relative to the biodegradable group and the biodegradable hydrophobic tail has the formula -R12-M1-R13, where R12 is a C4-C14 alkylene or C4-C14 alkenylene, M1 is the biodegradable group, R13 is a branched C10-C20 alkyl, and the total carbon atom content of the tail -R12-M1-R13 is 21 to 26;

in at least one hydrophobic tail, the biodegradable group is separated from a terminus of the hydrophobic tail by from 6 to 12 carbon atoms; and

the lipid has a pKa in the range of about 4 to about 11 and a logP of at least 10.1.

(Exhibit 1 at 538:13-38.)

ANSWER: Moderna admits that claim 18 of the '979 Patent recites the above claim language. Moderna otherwise denies the remaining allegations of Paragraph 25.

26. The '979 Patent has been owned by Alnylam at all times, is fully maintained, and is valid and enforceable.

ANSWER: Paragraph 26 states legal conclusions to which no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 26.

D. ALNYLAM PRESENTED CONFIDENTIAL INFORMATION REGARDING ITS PATENTED LNP TECHNOLOGY TO MODERNA IN 2014

27. In late-2013 or 2014, Alnylam and Moderna began discussions about a potential license to some of Alnylam's intellectual property along with a potential business relationship or a collaboration. Among the Alnylam intellectual property under consideration for license were the pending LNP Technology patent applications and all patents that would issue from such applications. On February 7, 2014, Moderna and Alnylam entered into a Mutual Confidentiality Agreement (the "Agreement"), allowing Alnylam and Moderna to share confidential information "for the purpose of enabling the other party to evaluate the feasibility or desirability of such business or research relationship." (Exhibit 6, § 1.) The Agreement stated that recipients of confidential information "shall not use or exploit such Confidential Information for its own benefit or the benefit of another without the prior written consent of the Disclosing Party." (*Id.* § 3.)

ANSWER: Moderna admits that Exhibit 6 purports to be a Mutual Confidentiality Agreement between Alnylam Pharmaceuticals, Inc. and Moderna Therapeutics Inc. dated February 7, 2014. *See* Exhibit 6. Moderna admits that Section 1 of Exhibit 6 states the following: "In the course of such discussions and negotiations, it is anticipated that either party may disclose or deliver to the other party certain confidential or proprietary materials or information for the purpose of enabling the other party to evaluate the feasibility or desirability of such business or research relationship." *Id.*, § 1. Moderna also admits that Section 3 of Exhibit 6 states the following: "The Recipient shall use such Confidential Information only for the Purpose for which it was disclosed as set forth above and shall not use or exploit such Confidential Information for its own benefit or the benefit of another

without the prior written consent of the Disclosing Party." *Id.*, § 3. Moderna denies the remaining allegations in Paragraph 27.

28. Pursuant to this Agreement, on or about April 28, 2014, Alnylam met with Moderna to disclose and discuss the Alnylam LNP Technology. Attendees from Moderna included Stephen Hoge (then Senior VP of Corporate Development), Said Francis (then Director of Business Development), Matt Stanton (then VP of Chemistry), and Örn Almarsson (then Senior VP of Formulation and Delivery Technology).

ANSWER: Moderna admits that on or about April 28, 2014, the following individuals met with Alnylam: Stephen Hoge (then Senior VP of Corporate Development), Said Francis (then Director of Business Development), Matt Stanton (then VP of Chemistry), and Örn Almarsson (then Senior VP of Formulation and Delivery Technology) attended this meeting. Moderna denies the remaining allegations in Paragraph 28.

29. In the April 28, 2014 meeting, Alnylam presented a detailed PowerPoint disclosing Alnylam's LNP Technology and how those LNPs could be used for developing RNA-based pharmaceuticals. Alnylam further disclosed valuable rodent and non-human primate pharmacology experiments that showed superior in vivo elimination of its biodegradable LNPs, while also showing superior potency.

ANSWER: Moderna denies the remaining allegations in Paragraph 29.

30. The discussions between Moderna and Alnylam continued through at least September 30, 2014. The discussions ended without Moderna agreeing to take a license to Alnylam's patents, patent applications, or trade secrets embodied in the Confidential Information on the Alnylam LNP Technology.

ANSWER: Moderna admits that apart from the Mutual Confidentiality Agreement between Alnylam Pharmaceuticals, Inc. and Moderna Therapeutics Inc.

dated February 7, 2014, no agreements exist between Moderna and Alnylam. Moderna denies the remaining allegations in Paragraph 30.

31. Upon information and belief, as of 2014, Moderna did not possess a cationic lipid with biodegradable groups sufficient to form a LNP with desirable properties to deliver RNA materials for use in therapeutics and vaccines. Upon information and belief, Moderna did not make the infringing SM-102 – a cationic lipid with biodegradable groups that uses the Alnylam LNP Technology – until sometime in 2015 for use in non-COVID vaccines Moderna was developing. (*See* Exhibit 7 at 8.)

ANSWER: Moderna denies the allegations in Paragraph 31.

E. MODERNA'S COVID-19 VACCINE

32. Upon information and belief, in either December 2019 or January 2020, Moderna began work on developing and formulating a vaccine for the prevention of the novel coronavirus (SARS-CoV-2). Despite lacking a license to the Alnylam LNP Technology, as part of that development and formulation, Moderna used its infringing LNP containing SM-102 to formulate and develop its COVID-19 Vaccine.

ANSWER:. Moderna admits that in early 2020 it began developing and formulating a vaccine for the prevention of the novel coronavirus (SARS-CoV-2). Moderna denies that its LNP containing SM-102 infringes the '979 patent. Paragraph 32 otherwise states legal conclusions to which no response is required. To the extent a response is required, Moderna denies the remaining allegations in Paragraph 32.

33. Upon information and belief, Moderna, working in conjunction with researchers from the NIH, finalized the mRNA sequence on January 13, 2020, for use as a potential vaccine against SARS-CoV-2. (*See* Exhibit 9 at 3.)

ANSWER: Moderna, Inc. admits that Exhibit 9 states "[t]he NIH and Moderna's infections disease research team finalized the sequence for mRNA-1273" on "Jan. 13, 2020." Exhibit 9 at 3. Moderna denies the remaining allegations in Paragraph 33.

34. Upon information and belief, the first clinical batch of Modena's vaccine candidate incorporating the SM-102 lipid was completed on February 7, 2020. The first patient in Moderna's Phase 1 clinical study received a dose on March 16, 2020. (*See* Exhibit 10 at 1.)

ANSWER: Moderna admits that Exhibit 10 states "[t]he first clinical batch [of SPIKEVAX®] . . . was completed on February 7, 2020." Exhibit 10 at 1. Moderna admits that Exhibit 10 also states "[t]he first participant in the [National Institute of Allergy and Infectious Diseases]-led Phase 1 study of mRNA-1273 was dosed on March 16, [2020]." *Id.* Moderna denies the remaining allegations of Paragraph 34.

35. Upon information and belief, Moderna filed its IND for its COVID-19 vaccine candidate comprising SM-102 on April 27, 2020. (*See* Exhibit 10 at 1.) On May 12, 2020, the FDA granted Fast Track status to Moderna's vaccine candidate. (*See* Exhibit 11 at 1.)

ANSWER: Moderna admits that Exhibit 10, a April 27, 2020 Moderna press release, states "Moderna, Inc., (Nasdaq: MRNA) a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today announced that it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug

Administration (FDA) for the company's mRNA vaccine candidate (mRNA-1273) against the novel coronavirus (SARS-CoV-2) . . . ." Exhibit 10 at 1. Moderna admits that Exhibit 11, an August 11, 2020 Moderna press release, states "On May 12, the FDA granted mRNA-1273 Fast Track designation." Exhibit 11 at 1. Moderna denies the remaining allegations of Paragraph 35.

36. On November 30, 2020, Moderna announced the results of its Phase 3 trial of its vaccine candidate comprising SM-102. (*See* Exhibit 12 at 1.) It announced on the same day that it would submit its Emergency Use Authorization to the FDA. (*See id.*)

ANSWER: Moderna admits that Exhibit 12, a November 30, 2020 Moderna press release, states "Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today announced that the primary efficacy analysis of the Phase 3 study of mRNA-1273 conducted on 196 cases confirms the high efficacy observed at the first interim analysis." Exhibit 12 at 1. Moderna admits that Exhibit 12 also states "[t]he Company also announced that today, Moderna plans to request an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) and conditional approval from the European Medicines Agency (EMA)." *Id.* Moderna denies the remaining allegations of Paragraph 36.

37. On December 18, 2020, the FDA granted an Emergency Use Authorization to Moderna's COVID-19 Vaccine comprising SM-102, under the

tradename "Moderna COVID-19 Vaccine," allowing commercial sales of its Covid-19 vaccine to commence. (*See* Exhibit 13 at 1.)

ANSWER: Moderna admits that Exhibit 13 purports to be a FDA News Release titled "FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for second COVID-19 Vaccine" dated December 18, 2020 and states "Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the second vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The emergency use authorization allows the Moderna COVID-19 Vaccine to be distributed in the U.S. for use in individuals 18 years of age and older." Exhibit 13 at 1. Moderna denies the remaining allegations of Paragraph 37.

38. On January 31, 2022, Moderna announced that it received FDA approval for its COVID-19 Vaccine, under the tradename SPIKEVAX®. (*See* Exhibit 14 at 1).

ANSWER: Moderna admits that Exhibit 14, a January 31, 2022 Moderna News Release, states "CAMBRIDGE, MA / ACCESSWIRE / January 31, 2022 / Moderna, Inc. (Nasdaq:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced the U.S. Food and Drug Administration (FDA) has approved the Biologics License Application (BLA) for SPIKEVAX (COVID-19 Vaccine, mRNA) to prevent COVID-19 in individuals 18

years of age and older." Exhibit 14 at 1. Moderna denies the remaining allegations of Paragraph 38.

39. On February 25, 2022, Moderna stated that it recognized $17.7 billion dollars in revenue in 2021 from sales of 807 million doses of its COVID-19 Vaccine. (Exhibit 3 at 100.)

ANSWER: Moderna admits that Exhibit 3 states "For the year ended December 31, 2021, we delivered approximately 332 million doses of our COVID-19 vaccine to the U.S. Government and approximately 475 million doses to other governments, and we recognized $17.7 billion in product sales." Exhibit 3 at 100. Moderna denies the remaining allegations of Paragraph 39.

F. ALNYLAM'S PATENTED LNP TECHNOLOGY IS ESSENTIAL TO MODERNA'S COVID-19 VACCINE

40. The patented Alnylam LNP Technology is essential to Moderna's COVID-19 Vaccine's efficacy and safety. The Vaccine's mRNA is very delicate and subject to rapid degradation by various enzymes upon administration. (*See* Exhibit 15 at 2.) The large, negatively charged mRNA strands also struggle to pass through the protective lipid membranes of cells. (*Id.*) Thus, to be effective, the mRNA strands need a delivery mechanism that can ensure that the mRNA strands are not degraded before delivery to the cell and can penetrate the cell. In addition, the LNP needs to be biodegradable, *i.e.*, such that the LNPs are metabolized and eliminated after successful mRNA delivery to the cells, so as to enhance safety.

ANSWER: Moderna denies that any of the technology claimed by the '979 Patent is included in the SPIKEVAX® vaccine. Moderna further denies that any technology claimed by the '979 Patent is essential to the efficacy and safety of the SPIKEVAX® vaccine. Moderna lacks the knowledge or information sufficient to

form a belief as to the truth of the remaining allegations of Paragraph 40 and on that basis denies the allegations.

41. Moderna turned to its SM-102 lipid to meet these requirements for its COVID-19 Vaccine. Moderna publicly recognized the central role biodegradable lipids in the LNPs play in the efficacy and safety of Moderna's COVID-19 vaccine. For example, Giuseppe Ciaramella, who was head of infectious diseases at Moderna from 2014 to 2018, has said that LNP technology "is the unsung hero of the whole thing." (*See* Exhibit 15 at 2.) Ciaramella credits the use of ester linkages to make the lipids more biodegradable to the success of Moderna's LNPs. (*Id.* at 6.) Those biodegradable properties and ester linkages employ the patented Alnylam LNP Technology.

ANSWER: Moderna admits that Exhibit 15 states: "LNP development has been a headache, but without this packaging, mRNA vaccines would be nothing. It is the unsung hero of the whole thing." Exhibit 15 at 2 (internal quotation marks omitted). Moderna denies the remaining allegations of Paragraph 41.

42. On July 21, 2020, Dr. Stephen Hoge, the President of Moderna, Inc., testified before the House Energy and Commerce Committee, Subcommittee on Oversight and Investigations about Moderna's COVID-19 Vaccine. In his testimony, he touted that "Moderna has developed a proprietary lipid-nanoparticle-delivery system that enhances safety and tolerability." (*See* Exhibit 16 at 4.) Moderna's "proprietary lipid-nanoparticle-delivery system" relies on the patented Alnylam LNP Technology.

ANSWER: Moderna admits that on July 21, 2020, Dr. Stephen Hoge, the President of Moderna, Inc., testified before the House Energy and Commerce Committee, Subcommittee on Oversight and Investigations about Moderna's COVID-19 Vaccine. Moderna admits that Exhibit 16 states "Moderna has developed a proprietary lipid-nanoparticle-delivery system that enhances safety and

tolerability." Exhibit 16 at 4. Moderna denies the remaining allegations of Paragraph 42.

43. On February 24, 2021, Stéphan Bancel, Moderna, Inc.'s CEO, publicly stated that its lipid system "is biodegradable, so it's a big competitive advantage for us." (*See* Exhibit 17 at 5.) The biodegradability of Moderna's lipid system employs the patented Alnylam LNP Technology.

ANSWER: Moderna admits that Exhibit 17 is an article that purports to contain a video transcript of an interview with Moderna's CEO, Stéphane Bancel that states "[s]o this early PEI that we invented in our labs that is biodegradable, so it's a big competitive advantage for us." Exhibit 17 at 5. Moderna denies the remaining allegations of Paragraph 43.

MODERNA'S INFRINGING ACTIVITIES

44. On information and belief, Moderna and/or its end users employ in its COVID-19 Vaccine SM-102, which meets every limitation of at least claims 18, 20-22, and 24-27 of the '979 Patent, in its COVID-19 Vaccine.

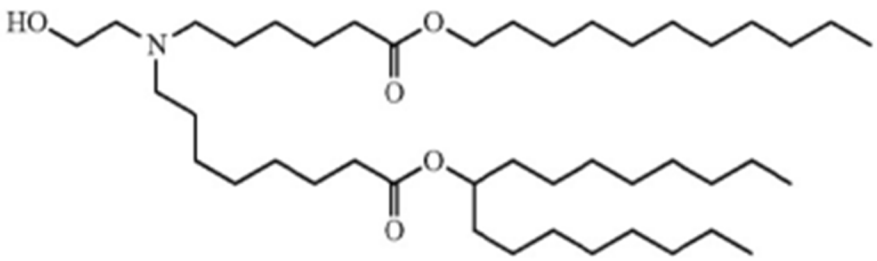
ANSWER: Moderna admits that the SPIKEVAX® vaccine contains SM-102. Moderna denies the remaining allegations of Paragraph 44.

45. The prescribing information, dated January 28, 2022, states that Moderna's Covid-19 Vaccine contains SM-102. (Exhibit 5 at 11.)

ANSWER: Moderna admits that Exhibit 5 purports to be a January 2022 version of the prescribing information for SPIKEVAX® (COVID-19 Vaccine, mRNA), which states "[e]ach 0.5 mL dose of SPIKEVAX also contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol

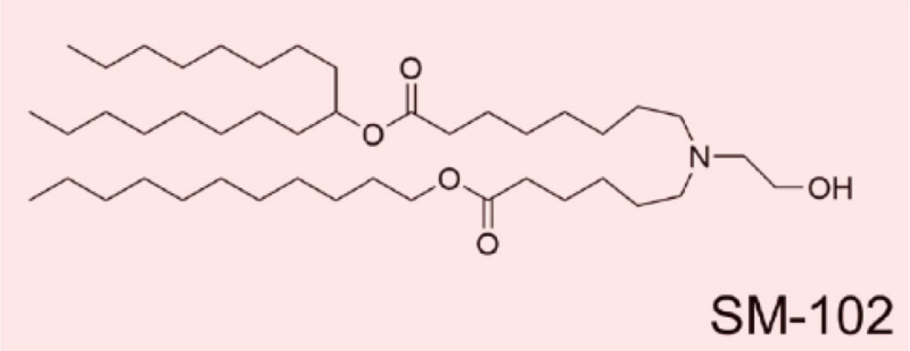
[PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.20 mg sodium acetate trihydrate, and 43.5 mg sucrose." Exhibit 5 at 11. Moderna denies the remaining allegations contained in paragraph 45.

46. Upon information and belief, and as described in publications, SM-102 is 9-heptadecanyl 8-{(2-hydroxyethyl)[6-oxo-6 (undecyloxy)hexyl]amino}octanoate and has the chemical structure:



(*See* Exhibit 8 at 3, 8.)

ANSWER: Moderna denies that Exhibit 8 describes SM-102 as "9-heptadecanyl 8-{(2-hydroxyethyl)[6-oxo-6 (undecyloxy)hexyl]amino}octanoate." Moderna admits that Exhibit 8 at 3 states "SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate}." Exhibit 8 at 3. Moderna also denies that Exhibit 8 depicts SM-102 as shown in the structure above. Exhibit 8, instead, depicts SM-102's structure as:



Id. at 8.

47. Upon information and belief, every dose of Moderna's COVID-19 Vaccine that it made, offered for sale, or sold contains SM-102, and will continue to do so.

ANSWER: Moderna admits that the SPIKEVAX® vaccine contains SM-102. Moderna denies the remaining allegations of Paragraph 47.

48. Attached as Exhibit 2 is a preliminary claim chart describing Moderna's infringement of claims 18, 20-22, and 24-27 of the '979 Patent. Exhibits 5, 8, 18, and 19 are supporting documents for the chart. The claim chart is not intended to limit Alnylam's right to modify the chart or allege that other activities of Moderna infringe the identified claim or any other claims of the '979 Patent or any other patents.

ANSWER: Moderna admits that Exhibit 2 of the Complaint purports to be Plaintiff's preliminary claim chart for claims 18, 20-22, and 24-27 of the '979 Patent. Moderna denies infringement of any claim of the '979 Patent and any remaining allegations of Paragraph 48.

49. Moderna has known of the '979 Patent since at least as early as February 15, 2022, when the '979 Patent issued.

ANSWER: Moderna admits that on or about February 15, 2022 it became aware of the '979 Patent. Moderna denies the remaining allegations of Paragraph 49.

FIRST CAUSE OF ACTION
(Infringement of the '979 Patent)

50. Alnylam realleges and incorporates by reference the allegations contained in the foregoing paragraphs.

ANSWER: Moderna incorporates by reference its responses contained in the foregoing paragraphs.

51. On information and belief, Moderna has infringed and will continue to infringe at least one claim of the '979 Patent, pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, selling, offering to sell or importing its COVID-19 Vaccine containing SM-102 within the United States and without authority.

ANSWER: Moderna denies the allegations of Paragraph 51.

52. Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. without authority have infringed and will continue to infringe at least one of the asserted claims of the '979 Patent pursuant to 35 U.S.C. § 271(b) by actively inducing the manufacturing, using, selling, or offering for sale within the United States or importing into the United States Moderna's COVID-19 Vaccine containing SM-102. Each of Defendant Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. intends that the others make, use, sell, offer to sell, distribute, export, and/or import Moderna's COVID-19 Vaccine and/or its components comprising the infringing SM-102 biodegradable lipid with the knowledge and specific intent that the others will directly infringe Alnylam's '979 Patent. Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. further intend that each end user, distributor, importer and/or exporter make, use, sell, offer to sell, distribute, export, and/or import Moderna's COVID-19 Vaccine and/or its components comprising the infringing SM-102 biodegradable lipid with the knowledge and specific intent that such end user, distributor, importer, and/or exporter end-users directly infringe Alnylam's '979 Patent.

ANSWER: Moderna denies the allegations of Paragraph 52.

53. Moderna's infringement has damaged and will continue to damage Alnylam, which is entitled to recover the damages resulting from Moderna's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

ANSWER: Moderna denies the allegations of Paragraph 53.

ANSWER TO PLAINTIFF'S PRAYER FOR RELIEF

Alnylam's Prayer for Relief does not require a response. To the extent a response is a required, Moderna denies that Alnylam is entitled to any relief whatsoever, whether as sought in its Prayer for Relief, or otherwise, in connection with this civil action.

MODERNA'S AFFIRMATIVE DEFENSES

Further answering the Complaint, Moderna asserts the following defenses without assuming any burden that they would not otherwise have, including without admitting or acknowledging that they bear the burden of proof as to any of them. Moderna reserves the right to amend its answer with additional defenses as further information is obtained.

FIRST AFFIRMATIVE DEFENSE

(NON-INFRINGEMENT OF THE '979 PATENT)

Moderna does not directly or indirectly infringe, either literally or under the doctrine of equivalents, and at all relevant times to this action has not infringed, any valid claim of the '979 Patent.

SECOND AFFIRMATIVE DEFENSE

(INVALIDITY OF THE '979 PATENT)

The '979 Patent is invalid for failure to satisfy one or more conditions and requirements of patentability set forth in 35 U.S.C. §§ 101 *et seq*. Each and every claim of the '979 Patent is invalid for failing to meet one or more of the requisite conditions of patentability specified in 35 U.S.C. §§ 101, 102, 103 and/or 112, or under any of the judicially created doctrines of invalidity.

THIRD AFFIRMATIVE DEFENSE

(NO WILLFUL INFRINGEMENT)

Moderna has not willfully infringed, and does not willfully infringe, any valid claim of the '979 Patent.

FOURTH AFFIRMATIVE DEFENSE

(FAILURE TO STATE A CLAIM)

Alnylam's Complaint fails to state a claim on which relief can be granted.

FIFTH AFFIRMATIVE DEFENSE

(PATENT MISUSE)

Alnylam has sought to enforce the '979 Patent for products and acts Alnylam knows are outside the claims of the '979 Patent, rendering the '979 Patent unenforceable on account of patent misuse.

SIXTH AFFIRMATIVE DEFENSE

(GOVERNMENT SALES)

Moderna incorporates by reference its briefing concerning Moderna's Partial Motion to Dismiss Pursuant to Federal Rule of Civil Procedure 12(b)(6) and the U.S. Government's Statement of Interest concerning 28 U.S.C. § 1498 and SPIKEVAX® doses made pursuant to the W911QY20C0100 Contract ("the C0100 Contract"). *See* D.I. 11; D.I. 12; D.I. 18; D.I. 56; D.I. 56-1; D.I. 78. Moderna's manufacture and sale of SPIKEVAX® pursuant to the C0100 Contract was and continues to be for the benefit of the U.S. Government and with the U.S. Government's authorization and consent under 28 U.S.C. § 1498(a). Accordingly, Plaintiffs' claims based on Moderna's manufacture and sale of SPIKEVAX® pursuant to the C0100 Contract are barred by 28 U.S.C. § 1498(a).

SEVENTH AFFIRMATIVE DEFENSE

(NO COSTS)

Plaintiff is barred by 35 U.S.C. § 288 from recovering any costs associated with this action.

EIGHTH AFFIRMATIVE DEFENSE

(NO EXCEPTIONAL CASE)

Moderna's actions in defending this case or otherwise does not give rise to an exceptional case in Plaintiffs' favor under 35 U.S.C. § 285.

NINTH AFFIRMATIVE DEFENSE

(PROSECUTION HISTORY DISCLAIMER AND ESTOPPEL)

Plaintiff is barred, based on statements, representations, and admissions made during prosecution of the patent applications resulting in the '979 Patents or related patent applications, from asserting any interpretation of any valid claims of the '979 Patent that would be broad enough to cover any accused product alleged to infringe the '979 Patents, either literally or by application of the doctrine of equivalents, or under any theory of infringement.

TENTH AFFIRMATIVE DEFENSE

(ESTOPPEL, WAIVER, ACQUIESCENCE, LACHES, AND UNCLEAN HANDS)

Plaintiff's claims and/or requested relief are barred by one or more of the doctrines of estoppel, waiver, acquiescence, laches, and unclean hands from enforcing, or claiming a reasonably royalty and/or lost profits with respect to any claim of the '979 Patents.

ELEVENTH AFFIRMATIVE DEFENSE

(PROSECUTION LACHES)

Plaintiff's claim and recovery of damages with respect to any claim of the '979 Patent are barred in whole or in part under the doctrine of prosecution laches.

TWELFTH AFFIRMATIVE DEFENSE

(35 U.S.C. § 271(e)(1))

Aspects of Moderna's alleged infringement of the '979 Patents are reasonably related to Moderna's development and submission of information to the FDA for the Emergency Use Authorization and the Biologics License Application regarding SPIKEVAX®. Accordingly, such claims for infringement against Moderna are barred by the safe harbor of 35 U.S.C. § 271(e)(1).

THIRTEENTH AFFIRMATIVE DEFENSE

(ADDITIONAL DEFENSES)

Moderna reserves the right to assert further defenses in the event that discovery indicates such defenses would be appropriate.

DEMAND FOR A JURY TRIAL

Moderna requests a jury trial for all issues so triable.

Dated: May 10, 2023

Respectfully submitted,

By: */s/ Michael J. Farnan*

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